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| 10/084,587      | 02/25/2002  | Edward J. Gavin      | 016866-008200US     | 6008             |

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EXAMINER

LAU, TUNG S

ART UNIT PAPER NUMBER

2863

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/084,587

Applicant(s)

GAVIN ET AL.

Examiner

Tung S Lau

Art Unit

2863

-- Th MAILING DATE of this communication appears on the cover sheet with the corresponding address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9. 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### Double Patenting rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-40 provisionally rejected under the judicially created doctrine of double patenting over claim 1-38 of copending Application No. 099999081. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: analyzes mass spectra using a digital computer, the method comprising: a) entering into a digital computer a data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes, each class characterized by a different biological status, and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio; and b) forming a classification

model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process comprising a recursive partitioning process.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 35, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27, 28, 19, 30, 31, 32, 33, 34, 37, 38, 39, 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Hillenkamp (U.S. Patent 6,558,902).

Regarding claim 1:

Hillenkamp discloses a method that analyzes mass spectra using a digital computer, the method comprising: a) entering into a digital computer a data set obtained from mass spectra from a plurality of samples, wherein each sample is,

or is to be assigned to a class within a class set comprising two or more classes (Col. 43-44, Lines 10-50, Col. 71, Lines 5-46), each class characterized by a different biological status (Col. 69, Lines 5-51), and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio (Col. 44-45, Lines 32-3) using laser ionization desorption process (Col. 4-5, Lines 52-26); and b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by executing code that embodies a classification process comprising a recursive partitioning process (Col. 44-45, Lines 32-3, Col. 69, Lines 5-51).

Regarding claim 35:

Hillenkamp discloses a computer readable medium a) code for entering data set obtained from mass spectra from a plurality of samples, wherein each sample is, or is to be assigned to a class within a class set comprising two or more classes (Col. 43-44, Lines 10-50, Col. 71, Lines 5-46), each class characterized by a different biological status (Col. 69, Lines 5-51), and wherein each mass spectrum comprises data representing signal strength as a function of time-of-flight, mass-to-charge ratio, or a value derived from time-of-flight or mass-to-charge ratio (Col. 44-45, Lines 32-3) using laser ionization desorption process (Col. 4-5, Lines 52-26); and b) forming a classification model which discriminates between the classes in the class set, wherein forming comprises analyzing the data set by

executing code that embodies a classification process comprising a recursive partitioning process (Col. 44-45, Lines 32-3, Col. 69, Lines 5-51).

Regarding claims 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, 18, 19, 21, 22, 23, 24, 25, 26, 27, 28, 19, 30, 31, 32, 33, 34, 37, 38, 39, 40:

Hillenkamp also disclose the use of MALDI (Col. 4-5, Lines 53-18), class consist of two classes (Col. 71, Lines 5-25), selected from group of Polypeptides and nucleic acids (abstract, Col. 71, Lines 5-24), selected from virus (Col. 69, Lines 13-51), normal and pathological status (Col. 69, Lines 13-51), un-diseased, low and high grade cancer (Col. 1, Lines 24-65), use a drug treated state, drug-responder and non-responder state (Col. 67, Lines 7-15), toxic and non toxic state (Col. 67, Lines 7-15), exposure to drug (Col. 67, Lines 7-15), is a known data set (Col. 69, Lines 13-51), pre-existing marker from classification (Col. 71, Lines 5-46), detecting signal of mass spectra in mass-to charge ratio (Col. 44-45, Lines 34-3), identifying features and different biological status (Col. 69, Lines 13-51), process is binary recursive partitioning process (Col. 78, Lines 34-53), interrogating classification for biological statues, using larger sample (Col. 71, Lines 5-46), use in a gas ion spectrometer (Col. 93-94, Lines 65-11), adopted to perform a laser desorption ionization process (Col. 93-94, Lines 65-11), a surface enhance desorption with antibodies (Col. 13-14, Lines 65-35, Col. 17, Lines 20-36). Using an unknown sample (Col. 64, Lines 36-63); repeat process (Col. 1-2, Lines 40-55); cluster analysis (Col. 91, Lines 18-29); using unknown sample (Col.

28, Lines 28-49); use of antibodies material (Col. 17, Lines 21-37), function derived from mass to charge ratio (Col. 44, Lines 32-50).

### ***Claim Objections***

3. Claims 16, 20, 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all the limitation of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: prior art fail to teach the use of neural network analysis, using raw data preprocessing.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tung S Lau whose telephone number is 703-305-3309.

The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on 703-308-3126. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-5841 for regular communications and 703-308-5841 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0956.

TC2800 FAX Telephone Numbers: 703-872-9306

TC2800 Customer Service FAX - (703) 872-9317

TL

December 29, 2003

  
John Baylow  
Supervisory Patent Examiner  
Technology Center 2800



ATTACHMENT

## Notice Regarding Benefit/Priority Claim(s)

### ☐ Improper Benefit Claim(s) to Prior-Filed Nonprovisional Application(s)

The benefit claim(s) to prior-filed nonprovisional application(s) is improper because there is no specific reference for each prior-filed application that includes: (1) the identification of the prior-filed application by application number, or international application number and international filing date; and (2) a clear indication the relationship (*i.e.*, continuation, divisional, or continuation-in-part) of the nonprovisional applications. For example, applicant should amend the specification to include a specific reference, such as "This application is a continuation of Application No. 10/---,--- filed ---." in the first sentence of the specification following the title.

Applicant should review each benefit claim submitted and, if appropriate, provide the proper reference to the prior-filed application(s) as required by 37 CFR 1.78. A proper relationship includes an identification of each nonprovisional application as a continuation, divisional or continuation-in-part application of the immediate prior-filed nonprovisional application for which a benefit is claimed under 37 CFR 1.78 in order to establish copendency throughout the entire chain of prior-filed applications. The specific reference must be included in the domestic priority information section of an application data sheet (37 CFR 1.76), or the specification must contain, or be amended to contain, such reference in the first sentence following the title.

**Timeliness:** The required reference for each benefit claim must be filed during the pendency of the instant application and within the later of: (1) four months from the actual filing date of the instant application, or the national stage commencement date if the instant application is a national stage application under 35 U.S.C. 371; or (2) sixteen months from the filing date of the prior-filed application. Failure to timely file the required reference is considered a waiver of any benefit claim, unless a grantable petition to accept an unintentionally delayed claim under 37 CFR 1.78(a), the surcharge set forth in 37 CFR 1.17(t), and the required reference are filed. See 37 CFR 1.78(a).

### ☐ Improper Benefit Claim(s) to Prior-Filed Provisional Application(s)

The benefit claim(s) to prior-filed provisional application(s) is improper because the instant application was not filed within twelve (12) months from the filing date of the provisional application, and there is no indication of an intermediate nonprovisional application that is directly claiming the benefit of the provisional application and filed within 12 months of the filing date of the provisional application. For example, applicant should amend the specification to include a specific reference, such as "This application is a continuation of Application No. 10/---,--- filed ---, which claims the benefit of U.S. Provisional Application No. 60/---,--- filed ---." in the first sentence of the specification following the title.

Applicant should review each benefit claim submitted and, if appropriate, provide the proper reference to the prior-filed applications (including an indication of any intermediate nonprovisional application that is directly claiming the benefit of the provisional application and filed within 12 months of the filing date of the provisional application) as required by 37 CFR 1.78. The required reference must be included in the domestic priority information section of an application data sheet (37 CFR 1.76), or the specification must contain, or be amended to contain, such reference in the first sentence following the title.

**Timeliness:** The required reference for each benefit claim must be filed during the pendency of the instant application and within the later of: (1) four months from the actual filing date of the instant

application, or the national stage commencement date if the instant application is a national stage application under 35 U.S.C. 371; or (2) sixteen months from the filing date of the prior-filed application. Failure to timely file the required reference is considered a waiver of any benefit claim, unless a grantable petition to accept an unintentionally delayed claim under 37 CFR 1.78(a), the surcharge set forth in 37 CFR 1.17(t), and the required reference are filed during the pendency of the instant application.

❑ **Improper Priority Claim(s) to Prior-Filed Foreign Application(s)**

The instant application was not filed within twelve (12) months from the filing date of the prior-filed foreign application, and there is no benefit claim to an intermediate nonprovisional application filed within 12 months of the filing date of the foreign application. Applicant should review each priority claim submitted and, if appropriate, provide the proper reference to any intermediate nonprovisional application filed within 12 months of the filing date of the foreign application in compliance with 37 CFR 1.78, or delete the priority claim. The required reference to an intermediate nonprovisional application must be included in the domestic priority information section of an application data sheet (37 CFR 1.76), or the specification must contain, or be amended to contain, such reference in the first sentence following the title.

**Timeliness:** The required reference for the benefit claim to an intermediate nonprovisional application must be filed during the pendency of the instant application and within the later of: (1) four months from the actual filing date of the instant application, or the national stage commencement date if the instant application is a national stage application under 35 U.S.C. 371; or (2) sixteen months from the filing date of the prior-filed application. Failure to timely file the required reference is considered a waiver of any benefit claim, unless a grantable petition to accept an unintentionally delayed claim under 37 CFR 1.78(a), the surcharge set forth in 37 CFR 1.17(t), and the required reference are filed.

❑ **Benefit Claims to More Than 400 Prior-Filed Applications**

The Office's automated system to record and capture benefit claims is only capable of recording benefit claims for 400 prior-filed applications. Therefore, the Office is unable to generate a filing receipt containing benefit claims for more than 400 prior-filed applications even though applicant is entitled to submit benefit claims for more than 400 prior-filed applications. Accordingly, applicant should not request a corrected filing receipt to include benefit claims for more than 400 prior-filed applications.

✓ **Prior-Filed Nonprovisional Application has been Improperly Indicated as a National Stage (35 U.S.C. 371) Application**

Applicant submitted a benefit claim to a prior-filed nonprovisional application and improperly indicated that the prior-filed application is a national stage application under 35 U.S.C. 371. The Office's records show that the prior-filed application is an application filed under 35 U.S.C. 111(a). The Office has entered the benefit claim to the prior-filed application as a benefit claim to an application filed under 35 U.S.C. 111(a). Any request for a corrected filing receipt to include the indication that the prior-filed application is a national stage application will not be granted unless applicant supplies evidence that the prior application was in fact a national stage application. Accordingly, applicant should not submit such request without such evidence. Applicant should submit an amendment (or an application data sheet (ADS) if the benefit claim was submitted in an ADS) to delete the indication that the prior-filed application is a national stage application.

For more information and examples on benefit claims, please see Claiming the Benefit of a Prior-Filed Application under 35 U.S.C. 119(e), 120, 121, and 365(c), 1268 Off. Gaz. Pat. Office 89 (March 18, 2003), which is available on the USPTO website at <http://www.uspto.gov/web/offices/com/sol/og/2003/week11/patbene.htm>, and the Manual of Patent Examining Procedure (MPEP) §§ 201.11 and 201.14.